DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#17

APR - 8 1994

Re: SUPPRELIN®
Docket No. 92E-0133

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,244,946, filed by The Salk Institute for Biological Studies, under 35 U.S.C. 156 et seq. The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent extension for SUPPRELIN® (histrelin acetate)that appeared in the Federal Register of June 2, 1992 (page 23237). The notice stated:

> FDA has determined that the applicable regulatory review period for SUPPRELIN® is 2,876 days. Of this time, 1,930 days occured during the testing phase of the regulatory review period, while 946 days occurred during the approval phase.

It should have stated:

> FDA has determined that the applicable regulatory review period for SUPPRELIN® is 2,878 days. Of this time, 1,931 days occured during the testing phase of the regulatory review period, while 947 days occurred during the approval phase.

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: James J. Schumann
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